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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,578	01/23/2001	Ilya Trakht	55099-B/JPW/KRD	2749

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/767,578	TRAKHT, ILYA	
	Examin r	Art Unit	
	Ron Schwadron, Ph.D.	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see enclosed action*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: *34*.

   Claim(s) rejected: *29-33*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *see enclosed action*

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PRIMARY EXAMINER
GROUP ~~1800~~ 1640

1. Claims 29-34 are under consideration.

2. It is noted that the specification defines "trioma" as a cell line formed from the fusion of three cells wherein a human-murine hybridoma is fused with a human lymphoid cell (see page 23, lines 19-24).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 29-33 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Oestberg et al. (US Patent 4,634,664) for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Oestberg et al. teach xenogeneic hybridoma fusion partners that do not produce antibody and the use of said cells as fusion partners to produce monoclonal antibodies upon fusion with an antibody producing cell (see column 2, last paragraph and column 3). Oestberg et al. teach that the nonantibody producing xenogeneic hybridoma fusion partner can be made by fusing a myeloma cell to a human lymphocyte (see column 2, last paragraph, continued on column 3). Oestberg et al. teach that the myeloma cell

used can be a hybrid cell formed from the fusion of two cells(see column 2, last paragraph). Thus, Oestberg et al. teach use of a three cell containing xenogeneic hybridoma fusion partner that does not produce antibody and the use of said cells as fusion partners to produce monoclonal antibodies. Oestberg et al. do not teach that the cell is a trioma as per the definition of the term in the specification (eg. "trioma" as a cell line formed from the fusion of three cells wherein a human-murine hybridoma is fused with a human lymphoid cell). Oestberg et al. teach heteromyeloma cell fusion partners (eg. mouse/human fused cells, see claim 14). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have produced the claimed method because Oestberg et al. teach the claimed method except for use of a trioma cell line formed from the fusion of three cells wherein a human-murine hybridoma is fused with a human lymphoid cell, Oestberg teach use of three cell nonantibody producing xenogeneic hybridoma fusion partner containing a hybrid myeloma cell and Oestberg et al. teach human heteromyeloma cells (mouse human hybrid myeloma cell line). One of ordinary skill in the art would have been motivated to do the aforementioned because Oestberg et al. teach use of hybrid myelomas as the fusion partner with a nonantibody secreting human lymphocyte (see column 2, last paragraph, continued on next page) to form a three cell nonantibody secreting fusion partner and also teaches heteromyeloma cell fusion partners (eg. mouse/human fused cells). The antibody producing hybrid cells can be used in vitro or in vivo to produce antibody (see claim 18). The cells are grown in vitro under conditions in which antibody is produced (see examples). Oestberg et al. teach freeze storage of desired antibody secreting cells (see column 7, penultimate paragraph). The various assay steps recited in claim 30 involve art known steps for immunoassays (see Examples in Oestberg et al.). The condition recited in claim 30 could be any of the art known diseases disclosed in column 4 of Oestberg et al.

Applicant has argued that Oestberg et al. teach use of a heterohybridoma, not a heteromyeloma. However, the specification appears to define said terms as interchangeable. The specification does not specifically define the terms heteromyeloma or heterohybridoma. However, as previously noted, the specification defines "trioma" as a cell line formed from the fusion of three cells wherein a human-murine hybridoma is fused with a human lymphoid cell (see page 23, lines 19-24). The specification also discloses that, "The present invention provides a trioma cell obtained

by fusing a heteromyeloma cell which does not produce any antibody with a human lymphoid cell." (page 3, lines 15-17). The only way these two statements can be reconciled is if the two terms (human-murine hybridoma (a.k.a. heterohybridoma) and heteromyeloma) are used interchangeably.

Regarding applicants comments in the amendment filed 9/29/2003, on page 5 of said amendment applicant argues that a heterohybridoma is not a heteromyeloma. However, on page 6 of said amendment, applicant argues that these two terms can encompass overlapping populations. Obviously, the aforementioned statements are not compatible. As previously discussed, the specification appears to define said terms as interchangeable. The specification does not specifically define the terms heteromyeloma or heterohybridoma. However, as previously noted, the specification defines "trioma" as a cell line formed from the fusion of three cells wherein a human-murine hybridoma is fused with a human lymphoid cell (see page 23, lines 19-24). The specification also discloses that, "The present invention provides a trioma cell obtained by fusing a heteromyeloma cell which does not produce any antibody with a human lymphoid cell." (page 3, lines 15-17). The only way these two statements can be reconciled is if the two terms (human-murine hybridoma (a.k.a. heterohybridoma) and heteromyeloma) are used interchangeably. Thus, the specification has implicitly defined the aforementioned terms as interchangeable.

The MPEP section 2173.05(a) states:

> TERMS USED CONTRARY TO THEIR ORDINARY MEANING MUST BE CLEARLY REDEFINED IN THE WRITTEN DESCRIPTION

Consistent< with the well-established axiom in patent law that a patentee >or applicant< is free to be his or her own lexicographer, a patentee >or applicant< may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings >if the written description clearly redefines the terms. See, e.g., Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) ("While we have held many times that a patentee can act as his own lexicographer to specifically define terms of a claim contrary to their ordinary meaning," in such a situation the written description must clearly redefine a claim term "so as to put a reasonable competitor or one reasonably skilled in the art on notice that the patentee intended to so redefine that claim term.");< Hormone Research Foundation Inc. v.

Genentech Inc., 904 F.2d 1558, 15 USPQ2d 1039 (Fed. Cir. 1990). Accordingly, when there is more than one definition for a term, it is incumbent upon applicant to make clear which definition is being relied upon to claim the invention. Until the meaning of a term or phrase used in a claim is clear, a rejection under 35 U.S.C. 112, second paragraph is appropriate. It is appropriate to compare the meaning of terms given in technical dictionaries in order to ascertain the accepted meaning of a term in the art. In re Barr, 444 F.2d 588, 170 USPQ 330 (CCPA 1971).

5. Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

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Ron Schwadron, Ph.D.
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